K091935

510(k) SUMMARY

PREPARATION DATE:	September 30, 2009
APPLICANT:	TearScience, Inc. 1101G Aviation Parkway Morrisville, NC 27560 Tel: (919) 467-4007 Fax: (919) 467-3300
CONTACT PERSON:	Christy Stevens, OD Vice President, Clinical and Regulatory Affairs
DEVICE TRADE NAME:	LipiView® Ocular Surface Interferometer
COMMON NAME:	Ophthalmic Imaging Device
CLASSIFICATION NAMES:	Ophthalmic Camera (21 CFR 886.1120) and AC-powered Slit Lamp Biomicroscope (21 CFR 886.1850)
DEVICE CLASSIFICATION:	Class II
PRODUCT CODES:	HKI and HJO
PREDICATE DEVICES:	1. OphthaVision Imaging System, MRP Group, Inc. (K980295; cleared May 19, 1998; Product Code HKI; 21 CFR 886.1120; Class II) 2. Tearscope-Plus, Keeler Instruments, Inc. (K973064; cleared April 7, 1998; Product Code HJO; 21 CFR 886.1850; Class II)

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DEVICE DESCRIPTION:

The LipiView® Ocular Surface Interferometer is a bench-top imaging device containing a computer system and electronics, chin rest and forehead rest, camera and zoom lens, illuminator and a touch screen display. The LipiView® Interferometer operates on the principle of white light interferometry and provides an interferometry color assessment of the tear film by specular reflection. The computer system captures a video image file that is recorded over time since the interference pattern changes as the tear film is distributed across the cornea during blinking. The video image of the ocular surface may be viewed on the computer screen display and in a printed report.

INTENDED USE

The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.

SUBSTANTIAL EQUIVALENCE TO THE PREDICATE DEVICES

The intended use and technologic characteristics of the LipiView® Interferometer are substantially equivalent to the OphthaVision Imaging System (K980295) and Tearscope-Plus (K973064). All three devices are prescription devices for imaging use by a physician during an in-office exam.

The LipiView® Interferometer and the OphthaVision Imaging System are intended to capture, archive, and manipulate digital images of the eye. The imaging focal plane with the LipiView® Interferometer is at the ocular surface and tear film, whereas the OphthaVision Imaging System can be used for intraocular imaging. Both devices provide a means to store digital images to allow a physician to monitor and photographically document conditions.

The LipiView® Ocular Surface Interferometer has similar technological characteristics to the OphthaVision Imaging System. Both devices use a digital camera, Microsoft Windows-based software, computer, monitor, graphical user interface, user controls, printer support, image storage drives, and AC power source. Both devices allow the user to select functions to process, analyze, archive and retrieve images. Analogous software features include image enhancement, alignment, comparison, animation, capture/save and print. The two devices store data in a similar Lossless file format.

Furthermore, the LipiView® Interferometer and the Tearscope-Plus have the same intended use to observe the tear film by specular reflection. Both devices allow the physician to observe tear film. The LipiView® Interferometer has similar technological characteristics to the Tearscope-Plus. Both devices use a diffuser and low-level white light to illuminate the eye on an angle and view real-time tear film dynamics. Both devices show the interference patterns for evaluation of the colors observed in the tear film. The LipiView® Interferometer and Tearscope-Plus are required to meet optical radiation safety standards.

The LipiView® Interferometer, OphthaVision Imaging System and Tearscope-Plus are all AC-powered devices that are required to meet electrical safety and electromagnetic compatibility standards. All three devices do not contact the patient's eye.

The LipiView® Interferometer includes a chin rest support system to position the patient's head during imaging, whereas the OphthaVision Imaging System and the Tearscope-Plus are used with a slit lamp biomicroscope that provides a chin rest support to position the patient's head. The chin rest support materials for the LipiView® Interferometer are widely used in ophthalmic slit lamp biomicroscopy products and are known for biocompatibility. Therefore, this difference does not raise new questions of safety and effectiveness. In addition, the LipiView® Ocular Surface Interferometer conforms to disinfection of patient contact surfaces for slit lamp biomicroscopes.

Minor differences in technology between the predicate devices and the LipiView® Interferometer do not raise new questions of safety and effectiveness and are supported by performance testing to applicable standards and software verification and validation. Table 5-1 compares the LipiView® Interferometer to the predicate devices.

PERFORMANCE TESTING:

The LipiView® Ocular Surface Interferometer conforms to the requirements under the applicable standards for slit lamp biomicroscopes; optical radiation safety; electrical safety; and material flammability. In addition, the LipiView® Interferometer is designed and will be manufactured in compliance with voluntary consensus standards for risk management and quality management systems. The LipiView® Interferometer software was developed and tested in compliance with FDA Guidance documents for software validation in medical devices.

CONCLUSIONS:

The LipiView® Ocular Surface Interferometer has comparable intended use and technologic characteristics to the predicate devices. Minor technological differences between the LipiView® Interferometer and the predicate devices do not raise new questions of safety and effectiveness and are supported by performance testing. TearScience has demonstrated through its evaluation of the LipiView® Ocular Surface Interferometer that the device is substantially equivalent to the predicate devices.

Table 5-1: Predicate Device Comparison Table			
Comparison Feature	**LipiView® Ocular Surface Interferometer**	**OphthaVision Imaging System (K980295)**	**Tearscope-Plus (K973064)**
Indications For Use	The LipiView® Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of specular (interferometric) observations of the tear film, which can be visually monitored and photographically documented.	The OphthaVision Imaging System is intended for use to capture, archive, and manipulate digital images of the eye obtained through use of an ophthalmic camera.	Specular observation of the tear film
Prescription/OTC Device	Prescription diagnostic	Prescription diagnostic	Prescription diagnostic
Method of Operation Ophthalmic Imaging	Ophthalmic camera with digital imaging system Graphical User Interface Touchscreen user control Microsoft Windows-based software	Ophthalmic camera with digital imaging system Graphical User Interface Mouse, keyboard and joystick user controls Microsoft Windows-based software	No software imaging capability
Method of Operation Tear Film Observation	Real-time tear film dynamics based on interference pattern from specular reflection Provides isolated tear film view and interferometric color analysis	None	Real-time tear film dynamics based on interference pattern from specular reflection
Illumination			
Source	Angled Class I white LEDs with diffuser	No direct illumination source Used with a slit lamp for illumination	Angled cold cathode light with diffuser May be used with a slit lamp, which provides additional illumination
Exposure Parameters	Illuminates lower half of eye Exposure and level of illumination complies with ISO 15004-2 Group 1 instrument for safety	Not applicable	Illuminates full eye including pupil Exposure level not specified Required to comply with safety standard
Brightness Control	No brightness control adjustment by user	Not applicable	High and low level brightness control
Material Flammability	Materials near light source comply with UL 94V-1	Not applicable	Not specified
Maximum Temperature of Held or Accessible Parts	Ambient temperature of parts of device held by operator or accessible to patient	Not applicable	Ambient temperature of parts of device held by operator or accessible to patient

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Christy Stevens, OD
VP, Clinical & Regulatory Affairs
Tearscience, Inc.
1101 G Aviation Parkway
Morrisville, NC 27560

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Re: K091935
Trade/Device Name: LipiView Ocular Surface Interferometer
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI, HJO
Dated: October 5, 2009
Received: October 6, 2009

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number: K091935

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K091935

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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